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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wright, J.L.C.
Appln. No. : 09/385,834
Filed: : August 30, 1999
Title : A Nutritional Supplement for Lowering
Serum Triglyceride and Cholesterol Level

Grp./A.U. : 1616
Examiner : S. N. Qazi

Docket No. : 76891

I hereby certify that this paper is being
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Patents, Washington, D.C. 20231, on this date.

Date 7/15/02 Gregory T. Shickles
Registration No. 27466
Attorney for Applicant (s)

Honorable Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR CONTINUED EXAMINATION PURSUANT
TO 37 CFR § 1.114 AND RESPONSE TO OFFICE ACTION
PURSUANT TO 37 CFR § 1.111

Dear Sir:

This is responsive to the Office Action dated April 26, 2002 concerning the
above-identified application. A request for continued examination under 37
CFR § 1.114 and the requisite fee under 37 CFR § 1.117(e) are submitted
herewith.

A Notice of Appeal was filed on April 15, 2002. Therefore, a petition for a
one-month extension of time under 37 CFR § 1.136(a) and the requisite fee
under 37 CFR § 1.117(a) for filing the Appeal Brief are submitted herewith.

Concerning 35 USC § 112

Claims 1, 5-11, 34 and 35 stand rejected under 35 USC § 112, second
paragraph as being indefinite on the grounds that the term "comprising" in
claim 1 is inclusive and fails to exclude unrecited steps. The Office Action
provides that the use of the term "comprising" to introduce claimed structure
means that the ingredients covered by these claims may involve more
elements than those positively recited.

Applicant respectfully traverses this rejection and submits that the instant claims are definite and unambiguous. Applicant respectfully submits that the use of the open-ended transitional term "comprising" is entirely acceptable and conventional patent claim drafting practice from which departure is made only when there is a need to exclude additional elements from the claims, through use of the closed transitional phrase "consisting of" or the semi-closed transitional phrase "consisting essentially of." Indeed, the use of the three standard transitional phrases is discussed with approval in the MPEP at § 2111.03.

Instant claim 1 clearly identifies the essential element of the claimed nutritional supplement — i.e. a sterol ester of an omega-3 fatty acid, wherein said omega-3 fatty acid is selected from the group consisting of EPA, DHA and SA. The open-ended transitional phrase "comprising" is properly used because the specification is clear that, in addition to the sterol ester of the omega-3 fatty acid, the nutritional supplement of the invention may include a wide range of additives. Various additives that may be included in the nutritional supplements of the invention are described in detail in the specification from page 8 line 30 through page 11 line 8. The specification is clear that, although such additives may advantageously be included in the nutritional supplements of the invention, they are not essential.

Applicant therefore respectfully submits that the instant claims properly define the nutritional supplements of the invention as being open to the inclusion of elements in addition to a sterol ester of an omega-3 fatty acid, but not requiring the presence of such additional elements. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1, 5-11, 34 and 39 stand rejected under 35 USC § 112, first paragraph, on the grounds that stearidonic acid recited in an amended claim 1 is not found in the specification, and is therefore considered new matter.

Applicant respectfully traverses this rejection. Explicit support for stearidonic acid is found in the specification as filed at page 6 lines 15-19 where it is stated that:

*More preferably, the omega-3 fatty acid is stearidonic acid
18:4 ω3 (SA), eicosapentaenoic acid....*

Reconsideration and withdrawal of the rejection of the claims under 35 USC § 112, first paragraph, are therefore respectfully requested.

Concerning 35 USC § 103

Claims 1, 5-11, 34 and 39 of record stand rejected under 35 USC § 103(a) as being obvious over U.S. Patent No. 5,770,749 to Kutney *et al.* and U.S. Patent No. 4,879,312 to Kamarei *et al.* The Examiner contends that Kutney *et al.* teach that phytosterols are effective in lowering plasma cholesterol levels and that Kamarei *et al.* teach that a diet rich in omega-3 fatty acids has beneficial effects in humans, including a reduction in plasma cholesterol and triglyceride levels etc.

The Examiner contends that the instant claims differ from the references in claiming a nutritional supplement by employing a combination of phytosterols and N-3 omega fatty acid, i.e. eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and stearidonic acid (SA).

The Examiner concludes that it would have been obvious to one skilled in the art at the time of the invention to employ phytosterols in combination with omega-3 fatty acids in compositions and methods for lowering cholesterol and triglycerides in the bloodstream of a subject, because these agents are known individually for the treatment of the same disorder.

Applicant respectfully traverses this rejection and submits that the present claims patentably distinguish from Kutney *et al.* and Kamarei *et al.* Applicant emphasizes that the instant claims are drawn not to a mere combination of a phytosterol and an omega-3 fatty acid, but rather to a sterol ester of an omega-3 fatty acid. The Examiner has not considered this limitation in the

claims. Applicant submits that, when evaluating the scope of a claim, every limitation in the claim must be considered (see MPEP § 2106 and *Diamond v. Diehr*, 450 US 175, 209 USPQ 1 (1981)).

Applicant respectfully submits that a *prima facie* case of obviousness concerning the instant claims drawn to nutritional supplements comprising a sterol ester of an omega-3 fatty acid, has not been made by the Patent Office. Kutney *et al.* discuss only phytosterols and do not mention omega-3 fatty acids. Conversely, Kamarei *et al.* discuss only omega-3 fatty acids, and do not discuss phytosterols. There is no suggestion or motivation to combine the references to arrive at the claimed combination.

Second, the references provide no reasonable expectation of success in using nutritional supplements comprising sterol esters of omega-3 fatty acids to reduce bloodstream cholesterol and triglyceride levels, as presently claimed.

Third, and most importantly, the references do not teach or suggest all of the limitations of the instant claims. In particular, neither reference makes any mention of esters, and neither reference, nor a combination thereof, teaches or suggests the claim limitation of a sterol ester of an omega-3 fatty acid.

Hence, Applicant respectfully submits that the cited references do not meet any one of the three basic criteria for a *prima facie* case of obviousness and that, for this reason alone, the rejection under claims under 35 USC § 103(a) must be withdrawn.

Moreover, as discussed in detail in the attached Declaration of H. Stephen Ewart, Ph.D., the claimed nutritional supplement comprising a sterol ester of an omega-3 fatty acid overcomes significant problems in the prior art, and does so with unexpected results.

In particular, in his Declaration, Dr. Ewart describes that:

- (1) A mere combination or mixture of a sterol and an omega-3 fatty acid results in a pasty composition that is not useful as a nutritional

supplement in the form of either a food additive or a pharmaceutical composition.

- (2) It was necessary to esterify the sterol to the omega-3 fatty acid to obtain a transparent, homogeneous oily liquid having properties useful as a nutritional supplement.
- (3) The mechanism by which sterols, such as phytosterols, reduce serum cholesterol, involves the failure of the sterol to be absorbed from the intestinal lumen into the bloodstream. The sterol inhibits cholesterol absorption in the small intestine by competing with cholesterol at critical points in the uptake process. In contrast, fatty acids such as omega-3 fatty acids are readily absorbed from the intestinal lumen into the bloodstream. It was not known, prior to the instant invention, whether, in the esterified product, the fatty acid moiety would increase the solubility of the sterol such that it would be absorbed into the bloodstream, negating its cholesterol lowering effect.
- (4) Conversely, in order to have a triglyceride lowering effect, the omega-3 fatty acid must be absorbed from the intestinal lumen into the bloodstream. It was not known, prior to the present invention, whether the sterol component of the ester would prevent the fatty acid from being absorbed into the bloodstream, negating its triglyceride lowering effect.
- (5) Finally, the balance of scientific evidence is that omega-3 fatty acids, while having a triglyceride lowering effect, actually increase cholesterol levels. Therefore, it was unexpected that the cholesterol-increasing effect of the omega-3 fatty acid would not cancel out the cholesterol-lowering effect of the sterol.

In view of the foregoing, Applicant respectfully submits that the cited references do not teach or suggest a nutritional supplement comprising a sterol ester of an omega-3 fatty acid as instantly claimed. Moreover, in view of the differing properties and mechanism of action of sterols and omega-3

fatty acids in regulating bloodstream cholesterol and triglyceride levels, it was unexpected and surprising that the nutritional supplements of the invention are useful for both lowering cholesterol and triglyceride levels in the bloodstream of a subject, as demonstrated by Applicant and as specified in the instant claims.

Reconsideration and withdrawal of the rejections of the claims under 35 USC § 103 are therefore respectfully requested.

Should the Examiner be of the view that a telephone conference would expedite prosecution of this application, she is respectfully requested to call the undersigned at the below-listed telephone number.

Respectfully submitted,

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